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SPECIAL ARTICLE

The age of competence: an update on the international laboratory accreditation scene for veterinary testing laboratories

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Abstract. Many changes have recently taken place in the world of laboratory accreditation. These changes include the increased use of voluntary standards in lieu of regulations, a move towards harmonization (equivalent results using voluntary standards) over standardization (using the same procedures or regulations), and an increased focus on competence, which includes the competence of laboratories to conduct testing, the competence of accreditation bodies to operate accreditation programs, the competence of bodies such as the National Cooperation for Laboratory Accreditation (NACLA) to recognize accreditation bodies as meeting the requirements of relevant standards, and the competence of organizations providing services to the accreditation process, such as the operation of proficiency testing programs. To describe these changes, a brief and general description of the International Laboratory Accreditation Cooperation accreditation scheme is provided, including an update on relevant decisions and activities in the United States and a description of the organization and activities of the newly formed NACLA. Following this discussion, with emphasis on veterinary testing, is an overview of several national and international organizations, including accreditation bodies, that promote harmonization, standardization, and analytical excellence. Also outlined are relevant activities of these organizations, an overview of some of the standards and guidelines they produce, and a description of how such organizations interact with each other and with laboratories seeking recognition for competence. Next is a brief discussion of recent developments and trends in laboratory accreditation, the impact of these developments, and the costs and benefits of accreditation to laboratories. Suggestions to veterinary laboratories for formulating strategy for keeping current with developments in accreditation and for determining quality goals are included.

The value system of what constitutes excellence in testing is changing. The focus on regulations, specific procedures, and individual credentials is changing to a focus on third-party verification of competence.

Many factors have influenced this trend, in particular national and international trade. Much work has been done in the establishment of science-based principles to promote a transparent and safe system for international trade.[27] The World Trade Organization (WTO) has recognized 3 international organizations as the relevant bodies for the setting of standards. The Office International des Epizooties (OIE) has been recognized as the relevant organization for setting animal health standards. The Codex Ailimentarius Commission (Codex), associated with the Food and Agricultural Organization (FAO) and the World Health Organization (WHO), sets standards for food safety and public health. The International Plant Protection Convention (IPPC) is to set plant health standards.

Supporting the use and value of third-party voluntary standards, accreditation, and harmonization are the Codex guidelines regarding the use of ISO/IEC (International Organization for Standardization/International Electrotechnical Commission) Guide 25[11] (now replaced by ISO/IEC International Standard 17025)[16] and ISO/IEC Guide 58,[12] recent publication by the OIE of a quality standard for laboratories,[24] the recent replacement of ISO/IEC 25 by ISO/IEC 17025, which combines the quality system elements of the ISO 9000 series[18–20] with technical requirements relevant to laboratories, and the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH) guides for biologics.[7–9] International standards endorsed by the OIE, the Codex, and the IPPC will be used as a benchmark by the WTO when evaluating national regulations.[27] The value of third-party voluntary standards has been recognized by the US government.[1] Harmonization (the move towards achieving equivalent results using voluntary standards) as opposed to standardization (using the same procedures or regulations) has become an important factor in the facilitation of trade. Although organizations such as the OIE recommend particular test methods for trade or for disease diagnosis and control[23] and proficiency testing programs may evaluate an analyst's ability to use a particular method, it is the laboratory's competence to conduct a defined scope of testing that is of primary interest.

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Competence: what is it?

Technical and operational competence, as it relates to a laboratory's ability to conduct testing, is determined by accreditation.

> *Accreditation.* A procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks (ISO/IEC Guide 2).[13]
>
> *Laboratory accreditation.* The formal recognition of the competence of a laboratory to carry out specific tests or specific types of tests.[13]

To define competence in the context of these terms, it is important to distinguish between accreditation and other terms, such as certification.

> *Certification.* Written assurance by a third party that a product, process, or service conforms to specified requirements.[13] This term is used internationally to include quality system or management system certification or registration. For example, a quality system can be certified (registered) as meeting the requirements of ISO 9001.

Accreditation uses ISO/IEC International Standard 17025 (currently being phased in from the use of ISO/IEC Guide 25). Accreditation looks at quality system requirements and technical competency requirements. To provide a clearer picture of what this means to a laboratory, the questions asked by a registrar's auditor and by an accreditation body's assessor can be compared:[25]

> The ISO 9000 Quality Systems Auditor asks, ''Have you defined your policies and procedures? Are they documented in accordance with the standard? Are you following them?''

This kind of audit and certification are designed to verify conformity, not technical competence.

> The Laboratory Accreditation Assessor asks, ''Have you defined and validated your procedures? Are they documented in accordance with the standard? Are you following them? Do your procedures ensure accurate and reliable results? Do you understand the science behind the procedures? Can you foresee and cope with any technical problems that may arise? Do you have the correct equipment? Do you have adequate personnel? Have you calculated your uncertainties or do you know the uncertainty inherent in your testing procedure?''

The concept of competence is therefore associated with the validity and with the understanding, by the laboratory staff, of the laboratory's procedures. It is also associated with the organization's capability to plan, to be proactive, and to ensure that its technical and management systems are effective in meeting predefined goals and objectives. The capability to understand is not only evaluated in the literal sense but is also assessed based on the ability to apply effectively, in a manner appropriate to the testing issue or problem of concern, applicable scientific principles. The logic of this approach is obvious when one realizes that proficiency testing is a snapshot and that an audit is based on a sampling. An accreditation body's assessment of capability and of competence may thus be seen as a more meaningful and valuable approach and may be more predictive of whether the use of a particular test method will yield valid test results of the desired accuracy and precision.

International Laboratory Accreditation Cooperation

A discussion on laboratory competence should begin with a description of the International Laboratory Accreditation Cooperation (ILAC) because the harmonization of international accreditation schemes derives from it. Formalized as a cooperation in 1996, ILAC is an international cooperation among the laboratory accreditation schemes in almost all nations. ILAC requires accreditation bodies to use ISO/IEC International Standard 17025, ''General requirements for the competence of testing and calibration laboratories.'' The ILAC system also relies on the use of ISO/IEC Guide 58 to determine the competence of accreditation bodies. ILAC fosters multilateral recognition among members for the enhancement and facilitation of acceptance of international test data. This approach allows countries with similar accreditation systems to establish agreements among themselves. These agreements, called mutual recognition arrangements (MRAs), include mutual evaluation and acceptance of each other's accreditation systems as equivalent. MRAs enable accredited laboratories to achieve a form of international recognition, thereby allowing test data accompanying exported goods to be more readily accepted.

ILAC members may participate on and contribute to the working committees and to committee-established working groups. These working committees conduct the work of ILAC, including the production of ILAC guidelines. ILAC publishes an extensive range of documents and guides to assist accreditation bodies, laboratories, trade and regulatory bodies, and other interested parties. These guidelines cover accreditation practices and subjects such as traceability, legal liability, and trade issues related to testing and international agreements. ILAC guidelines therefore determine what accreditation bodies will ask of laboratories.

Laboratory conformity assessment in the United States

In 1996, Congress passed the National Technology Transfer and Advancement Act, which gave the National Institute of Standards and Technology (NIST, Department of Commerce) the responsibility for coordinating conformity assessment in the United States. One of the more complex conformity assessment activities in the United States is laboratory accreditation.

To address the need for coordination and consistency in this area, NIST, other government agencies, and a number of private entities incorporated the National Cooperation for Laboratory Accreditation (NACLA) in 1998. NACLA is a not-for-profit organization in which both the public and private sectors are involved. NACLA evaluates laboratory accreditation bodies and grants recognition to those that are in compliance with ISO/IEC Guide 58. NACLA, an ILAC member, bases its operations and requirements on ILAC guidelines and works with the ILAC P2 document.[10] NACLA serves as the focal point for laboratory accreditation in the United States and develops and represents US positions on laboratory accreditation within the international community. NACLA is now working to have its recognized accreditation bodies accepted by all participants in the ILAC system.

Accreditation bodies

A laboratory seeking recognition for competence and a trading partner concerned about the validity and reliability of test results will be concerned about the value of the certificate of accreditation on a laboratory's wall. Therefore, accreditation bodies must also demonstrate competence in accrediting laboratories and must do so in a way that will obtain the widest possible international recognition of the accreditation.

Obtaining recognition by a body such as NACLA is no small feat. Requirements for recognition center around the comprehensive requirements of ISO/IEC Guide 58. Guide 58 includes requirements for the organization of the accreditation body, for its quality system, for how the accreditation body grants, maintains, extends, suspends, and withdraws accreditation, for its documentation, for its requirements for laboratory assessors, for how assessors are qualified and contracted, and for how the accreditation process is handled (from application to granting accreditation, including surveillance and reassessment).

Some of the many accreditation bodies that use ISO/IEC International Standard 17025 for accreditation and operate under the requirements of ISO/IEC Guide 58 are the National Voluntary Laboratory Accreditation Program (NVLAP), United States; the American Association for Laboratory Accreditation (A2LA), United States; the Standards Council of Canada (SCC), Canada; and the National Association of Testing Authorities (NATA), Australia. Accreditation bodies such as these have web sites that offer excellent technical guidance for laboratories implementing the requirements of ISO/IEC 17025. Such guidance includes special program documents, checklists, standards, guides, and information on the accreditation process itself.

Many accreditation bodies have developed or are developing additional accreditation programs based on standards or guides other than ISO/IEC 17025 for activities other than testing. The most notable of these is accreditation for operating a proficiency testing program. Some accreditation bodies will also accredit or are preparing to recognize or accredit the providers of reference materials and laboratories wishing to demonstrate competence to conduct research, test method development, and/or test method evaluation (e.g., the SCC). Some accreditation bodies have also developed special programs for laboratories performing testing in certain fields or disciplines. For example, the A2LA has developed several special programs, including those for food microbiology and food chemistry. Special programs add additional requirements to those of ISO/IEC 17025. These typically include technical specifications for the diagnostic discipline or technical area involved.

Collaboration of accreditation bodies and specifiers

Specifiers (those who set specifications, e.g., government agencies) might well consider whether the services of a recognized accreditation body could assist in the recognition of testing laboratories (e.g., those testing services that the specifier and specifier laboratories may be required to ''certify'' or oversee according to their mandate and/or according to their responsibilities under regulations) and whether the services of a recognized accreditation body might facilitate or ensure the international recognition needed for trade. Accreditation bodies can work with specifiers to assist them in executing their responsibilities. Restricted budgets may prevent government agencies from doing any testing themselves, and programs may have to rely solely on third-party laboratories. In other cases, specifier laboratories may retain some testing functions. Collaboration with a recognized accreditation body may therefore take many levels and forms, according to need. This collaboration may, for example, involve the creation of a special program and/or the use of the specifier's test methods, proficiency testing programs, training, and/or auditors and assessors. The extent of involvement may vary in each case, according to factors such as regulatory and trade requirements, budgets, needs, and preferences. Such collab-

orations and partnerships can assist the specifier in creating a national system and in acquiring the recognition needed for acceptance of test results. More importantly, this combination of specifier technical competence and accreditation body competence may provide better specifier oversight while saving specifier resources.

Third-party accreditation can provide a fair and meaningful basis for the identification of competent laboratories. Accreditation generally leads to higher standards of quality in laboratories and, therefore, to more effective regulations.[25] Specifiers' laboratories themselves are working towards accreditation.[26]

Acceptance of specifier-developed, -validated, -evaluated, and/or -endorsed test methods may be enhanced or broadened by specifier laboratory accreditation. Acceptance may also be achieved by specifier partnership or collaboration with a reputable technical body, such as the AOAC International (previously the Association of Official Analytical Chemists), in the production of fully validated test methods.

Some organizations that produce standards, guides, and test methods useful for veterinary testing laboratories

Following is a list of organizations whose activities are relevant, directly or indirectly, to advancing the technologies and management processes pertinent to the improvement and/or recognition of veterinary laboratory test results and that may produce standards, guides, and/or test methods useful to those laboratories seeking to demonstrate competence. Where pertinent, a very brief description and discussion of some of the more useful documents produced by the organization is included. A comprehensive list of organizations and documents is beyond the scope of this article. The organizations listed here are meant to serve as examples and were chosen because they may aid the veterinary testing laboratory in demonstrating competence. These organizations and many others now have very detailed and comprehensive web sites, where information on their activities and documents may be obtained.

Many organizations listed (e.g., AOAC International) offer information and courses concerning the ISO/IEC 17025 standard and its implementation. These organizations may also offer other courses helpful to laboratories seeking accreditation.

Accreditation bodies (recognized by NACLA and/or according to ILAC guidelines). As previously stated, these bodies have web sites that offer excellent guidance for laboratories implementing the requirements of ISO/IEC 17025.

American Association of Veterinary Laboratory Diagnosticians (AAVLD). The stated purposes of this organization include the dissemination of information relating to the diagnosis of animal disease, the establishment of uniform diagnostic techniques, the improvement of existing techniques, the development of new diagnostic techniques, and the establishment of guidelines for the improvement of diagnostic veterinary laboratory organizations. The AAVLD has operated a laboratory accreditation program (not recognized by NACLA) for several years. It serves as consultant to the US Animal Health Association on diagnostic criteria. The AAVLD may be regarded as a valuable source of information and services for veterinary laboratories seeking to demonstrate competence.

AOAC International. Previously the Association of Official Analytical Chemists, the AOAC International is a proactive, worldwide provider and facilitator of the development, use, harmonization, and publication of validated analytical methods and laboratory quality assurance programs and services. Its primary focus is on chemical and microbiological food contaminants. The AOAC International is not an accreditation body. However, members of the AOAC Laboratory Accreditation Criteria Committee are working to provide laboratory managers with the tools they need to meet the requirements of ISO/IEC 17025. The accredited AOAC Laboratory Proficiency Testing Program is also playing a key role.

College of American Pathologists (CAP). CAP manages an accreditation and proficiency testing program (not recognized by NACLA) and produces guides and criteria. Some of this material and some of the proficiency tests may be useful to veterinary laboratories.

Co-Operation on International Traceability in Analytical Chemistry (CITAC). CITAC arose out of a workshop held at the Pittsburgh Conference in 1993. CITAC fosters collaboration between existing organizations to improve the international comparability of chemical measurement. Important publications have addressed traceability,[4] the quantification of uncertainty,[5] quality assurance in the routine environment,[2] and quality assurance for research, method development, and nonroutine analysis,[3] which is important for veterinary laboratories. Veterinary laboratories doing nonroutine testing, such as that done for the diagnosis of foreign animal diseases, may find this last document useful in implementing a quality system.

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH). Launched in 1996, VICH is a trilateral (European Union, Japan, United States) program aimed at harmonizing technical requirements for veterinary product registration. VICH produces guidelines useful to those interested in the registration of veterinary products and to laboratories interested in implementing the requirements of ISO/IEC 17025. Po-

tentially useful guidelines include GL1,[7] GL2,[8] and GL9.[9]

International Laboratory Accreditation Cooperation. As discussed above, ILAC guidelines determine what accreditation bodies will ask laboratories to do.

International Organization for Standardization. A cooperation between virtually every industrialized country in the world, ISO produces thousands of standards and guides, including the 9000 series[18–20] for quality management systems, ISO/IEC 17025,[16] and microbiological and chemical test methods. ISO and the IEC form a specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of ISO standards through their technical committees, and ISO and IEC committees collaborate. Other international organizations also take part in the work.

A full list of ISO guides and standards relating to laboratory accreditation and to laboratory testing would be extremely long and is beyond the scope of this article. The ISO web site lists guides and standards that cover many topics. A few of these guides and standards will be particularly useful to veterinary laboratories seeking accreditation. The normative references and bibliographies of these documents will also be useful.

Of greatest interest to laboratories seeking recognition for competence is ISO/IEC International Standard 17025.[16] A comprehensive and detailed standard, its requirements include adequate facilities, accurate equipment, qualified staff, appropriately validated test methods, and a comprehensive and effective quality management system. Testing and calibration laboratories that comply with ISO/IEC 17025 are considered to also operate in accordance with ISO 9001 or 9002 (1994), normative references of ISO/IEC 17025.

The revised ISO 9000 series,[18–20] published in 2000, represents a significant change in the way this group of international standards is organized. The third edition of ISO 9001 (2000) replaces the second edition (1994) and 9002 (1994). ISO 9001 contains requirements for quality management systems. It is not a competence standard. However, laboratories implementing the requirements of ISO/IEC 17025 will find this series very valuable for creating, implementing, monitoring, and managing the quality management system required by ISO/IEC 17025. Especially useful are the ISO standards listed in the bibliographies, which provide guidance in setting up and monitoring specific areas of a quality management system.

ISO/IEC Guide 43, parts 1 and 2,[14,15] deal with proficiency testing by interlaboratory comparisons. ISO/IEC Guide 43 is the basis for the requirements of accreditation bodies for the accreditation of providers of proficiency testing schemes. Part 1 contains guidelines for the development and operation of proficiency testing programs. This guide is especially useful for specifier laboratories or bodies required or wishing to create and manage such programs. Although this guide was written to deal with interlaboratory comparisons, it will also be useful to any laboratory setting up an internal proficiency testing program. Part 2 provides guidance for the selection and use of proficiency testing schemes by laboratory accreditation bodies. Laboratories seeking accreditation will find this document useful for understanding and preparing to meet the requirements of the selected accreditation body. Specifiers required to create and manage proficiency testing programs will also find this guide helpful.

ISO Guide 34[17] includes requirements for the competence of producers of reference materials and contains quality system and technical requirements. Specifier laboratories that produce such materials will find this guide useful. Because proficiency test samples may be considered reference materials, providers of such samples should consider the necessity of obtaining accreditation or verification of competence to produce reference materials.

ISO/IEC Guide 58[12] is used to determine the competence of accreditation bodies.

International Union of Pure and Applied Chemistry (IUPAC). IUPAC, working toward harmonization of quality assurance schemes for analytical laboratories in conjunction with ISO and the AOAC International, has produced several potentially helpful technical reports and communications.[6,28,29]

National Cooperation for Laboratory Accreditation. NACLA is a valuable source of information for laboratories interested in accreditation.

NCSL International. NCSL International was formed in 1961 (as the National Conference of Standards Laboratories) to promote cooperative efforts for solving the common problems faced by measurement laboratories. Its mission is to advance technical and managerial excellence in the fields of metrology, measurement standards, equipment calibration, and test and measurement. NCSL International publishes valuable standards and guides. Organizations such as NCSL International can provide guidance to veterinary laboratories on setting up a technically valid and NIST-traceable calibration program.

Office International des Epizooties. The OIE has produced many important standards and guides, 2 of which provide direct guidance to veterinary laboratories seeking to demonstrate competence. The *OIE manual of standards for diagnostic tests and vaccines*[23] has several introductory chapters that cover certain critical aspects of laboratory management and competence, including one on the quality management of veterinary laboratories. Based on ISO/IEC 17025,

the recently published *OIE standard for management and technical requirements for laboratories conducting tests for infectious animal diseases*[24] includes some specific requirements relevant to veterinary laboratories.

Organisation for Economic Co-operation and Development (OECD). Located in Paris, the OECD currently has 30 member countries that work together to seek answers to common problems and coordinate domestic and international policies. This work may lead to formal agreements, better information, and clarification of the impact of national policies on the international community. The OECD has published guidelines for good laboratory practice.[22] Designed primarily for the conduct of toxicologic studies, this document and the others from the same series may be useful to laboratories looking for ways to set up quality systems in research and test development. These documents may also provide assistance in setting up systems to fulfil the test validation requirements of ISO/IEC 17025.

Other standards, guides, and technical organizations. Although many standards and guidelines have been listed here in the context of a brief discussion of their owner or sponsor organization, there are many more of each that are approachable and/or available. A search of organizations' publications and offerings on a particular topic of interest will yield many more documents, as will an Internet search using a particular technical or quality topic. For example, for test validation, one may find additional useful guidance from the US Pharmacopoeia, from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, and in US government regulations (e.g., Code of Federal Regulations, Title 21, 58.29). For those laboratories wishing to demonstrate competence in a particular technical or operational area, more guidance is available than ever before from respected national and international sources.

Recent changes and trends

Several changes have recently been implemented that will be important to those who seek accreditation.

1. ISO/IEC International Standard 17025 replaced ISO/IEC Guide 25 and EN45001 (a European standard) in December 1999.
2. The next version of ISO/IEC 17025 is expected to absolutely require laboratory participation in external proficiency testing programs. Accreditation bodies generally require this now, regardless of the lack of an absolute requirement in the current version.
3. ISO/IEC Guide 58 will be retired and will be replaced by ISO/IEC International Standard 17011.[21]
4. ISO 9000[18–20] was recently issued and represents a significant change in the way this international standard is organized. ISO/IEC 17025 will be merged with ISO 9001:2000. A special IEC committee (ISO/CASCO WG 25) has recently been formed to develop this project.
5. ILAC has recently produced several new guides. Readers are encouraged to consult the ILAC web site and to note how many of these documents include ''competence'' in the title.
6. Accreditation bodies are now including in their services the accreditation of proficiency testing providers. Proficiency testing, as a requirement for laboratory accreditation and an activity of providers and accreditation bodies, has become an issue of intense interest to accreditation bodies and to bodies such as NACLA.
7. ISO Guide 34 was published in 2000.[17] Producers of samples for proficiency testing programs may be considered to be providing reference materials. The recognition of competence of laboratories involved in this area of operation will become an even greater issue.
8. There is more focus by accreditation bodies on measurement uncertainty and on its determination or calculation. Knowledge of the uncertainty of testing procedures is now a significant requirement for biological and chemical laboratories as well as calibration laboratories.

Impact of these developments and trends on testing laboratories

The replacement of ISO/IEC 25 by ISO/IEC 17025 has had a significant impact on testing laboratories because its requirements are more comprehensive, particularly with regard to the management system requirements. Testing laboratories must also be aware of the requirements for accreditation of providers of proficiency testing programs. It is and will become more important to choose an accredited provider. Requirements for calibration and traceability, both as stated in ISO/IEC 17025 and as required by accreditation bodies, have become an important factor for testing laboratories performing their own calibrations, for the selection of calibration laboratories to do work for these testing laboratories, and for the use of vendors performing calibration, maintenance, and repair of laboratory equipment.

Impact of these developments and trends on the national reference laboratories of specifiers

The current and predicted necessary competences of a national reference laboratory such as the National Veterinary Services Laboratories and Center for Veterinary Biologics Laboratory, in Ames, Iowa, have re-

cently become a formidable list. Based on the services they may be expected to provide, such laboratories must consider the necessity of being able to demonstrate competence in the conduct of routine testing, nonroutine testing, and test method development, validation, and evaluation, the conduct of research, the production and analysis of data, the performance of calibrations, the creation of reference materials, and the operation of proficiency testing programs. The conduct of training and oversight may well be added to this list and is particularly appropriate if technical assessors are to be provided by the laboratory for a national accreditation program designed to be executed in collaboration with a recognized accreditation body.

The need to demonstrate competence has affected the strategy and decisions of several government agencies.[26] Although accreditation for testing is widely available, specifics for obtaining accreditation or recognition for some of the other competences are not as well defined or developed. However, accreditation bodies are prepared or are preparing to meet these needs.

Benefits of accreditation for laboratories

The general benefits of accreditation include[25] increased productivity, improved performance, increased morale of staff, credentials to qualify for testing work, ability to compete in some markets, an objective third-party assessment, recognition and acceptance for competence, increased ability to stay abreast of developments in requirements for competence and testing, and possible decreases in the cost of liability insurance.

Costs of accreditation

Accreditation has associated costs that will vary, the details of which are beyond the scope of this article. Major factors affecting the cost of accreditation include the size of the laboratory, the location of the laboratory, the scope, type, and field(s) of testing to be listed on the certificate of accreditation, the gap between the status of the laboratory and the requirements for accreditation, and the fees required by the selected accreditation body. Information on fees may be obtained from each accreditation body. Each laboratory, having approximated the cost of accreditation, should also carefully consider the cost of not having the accreditation.

Summary and strategy

The world is moving towards harmonization via the use of third-party voluntary standards. Test result acceptance for trade will be based on the accreditation of laboratories by recognized accreditation bodies based on internationally accepted standards. The requirements of such standards are based upon competence.

Veterinary laboratories should formulate strategies for keeping current with developments in the requirements for and assessment of competence. Strategies should include a plan for checking development of new standards that relate to the accreditation of laboratories. The laboratories should, of course, also stay current with relevant technical standards. Better still, veterinary testing laboratories are urged to help determine the content of relevant standards and guides by membership in technical organizations and bodies involved with laboratory accreditation, attendance at their meetings, and involvement in their activities.

Each laboratory should carefully decide, based upon its own situation (e.g., costs, risks, mandate, vision, mission, activities, and products), the level of quality assurance it should implement, on the scope of the quality management system (scope in this instance includes the locations, activities, fields, disciplines, standards, metrologic specifications, and/or tests to which the quality management system will apply), and the level and type of recognition it needs. Accreditation by a recognized accreditation body will result in the widest recognition for the laboratory and will provide the general benefits previously listed.

Governments and their laboratories should determine whether they would benefit by collaboration with a recognized accreditation body in executing their duties, as established by regulations and by the programs the laboratories serve. Accreditation bodies can be helpful in making such determinations.

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